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M PAUL BAKER ESQ
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP
1300 I STREET NW
WASHINGTON, DC 20005-3315

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,421	YOSHINAGA, STEVEN K.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42,43 and 48* is/are allowed.

6)☒ Claim(s) *39-41, 4-47 and 49-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.
Applicant's submission filed on 1/26/04 has been entered.

Applicant's amendment, filed 1/26/04, has been entered.
Claims 1-38 have been canceled.
Claims 39-58 have been added.

Claims 39-58 as they relate to nucleic acids encoding a B7RP1 polypeptide (SEQ ID NOS: 6, 11 and 16) are under consideration in the instant application.

2. This Office Action will be in response to applicant's arguments, filed 1/26/04
The rejections of record can be found in the previous Office Actions.

Sequence Compliance

3. Applicant's provision of a Paper Copy of the Sequence Listing, a corrected CRF, and a Statement that the Paper Copy and CRF are identical is acknowledged.

The instant application is in compliance with the Sequence Rules.

Priority

4. Applicant is invited to verify that the instant claims have written support and enablement under 35 USC 112, first paragraph, for the instant claims to priority documents USSN 09/264,527 and 09/244,448. The instant claims may not have the benefit under 35 U.S.C. § 120 of all of the priority filing dates.

For example, it is not clear that all of the claimed SEQ ID NOS. have written support back to to priority documents USSN 09/264,527 and 09/244,448. For example, priority document USSN 09/264,527 was filed with only 9 Figures (compared to the current number of 23 drawings) and was not in sequence compliance.

Also, it is not clear whether the fragment language (e./g. "at least about 50/75 amino acid residues" as well as the specific residues recited (e.g. claims 40(b), claim 41(b), claim 44, claim 45, claim 46) and the "95% identical to an amino acid sequence as set forth in Figure 12A (SEQ ID NO: 17)" have written support back to priority documents USSN 09/264,527 and 09/244,448.

Applicant should present a detailed analysis as to why the claimed subject matter has clear support in the priority applications.

5. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Rejections - 35 USC § 112 second paragraph

6. Applicant's cancellation of the previous claims have obviated the previous rejections under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

8. Claims 39-41, 44, 46,47, 49-51 and 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 39-41, 44, 46,47, 49-51 and 52-58 are indefinite in their recitation of a nucleic acid encoding polypeptides and polypeptide fragments having "a T cell proliferation activity" "a T cell activation activity" and "binding activity to CRP1" Although the specification discloses on page 43 at lines 12-23 that binding to a CRP1 polypeptide and the ability to stimulate T cell proliferation and/or activation are activities which are characteristic of a B7RP1 polypeptide, the current recitation is ambiguous in the manner it sets forth the various activities.

It is suggested that applicant amend the claims to a recitation of clear positive activities such as "stimulates T cell proliferation", "stimulates T cell activation" and "binds to CRP1" which is consistent with the disclosed activities on pages 41-42, overlapping paragraph of the instant application. As noted previously, applicant has been cautioned that recitation of the term "CRP1", also an arbitrary protein name, which is considered indefinite as set forth previously for the term "B7RP1".

B) Claims 39-41, 44, 46,47, 49-51 and 52-58 are indefinite in that they recite an arbitrary protein name, "CRP1". The specification does not appear to provide an explicit definition of the term "CRP1" since "all related polypeptides described herein", including polypeptides which do necessarily share substantial structure or function with the polypeptides set forth in SEQ ID NOS: 2 or 22, are encompassed in the description of a "CRP1 polypeptide" disclosed on pages 41-42 of the specification.

Applicant should particularly point out and distinctly claim "CRP1" by claiming a sufficient number of characteristics associated with the protein (e.g. SEQ ID NOS).

C) Claim 51 is indefinite in its recitation since it is not clear how an amino sequence that is "at least about 95% identical to an amino acid sequence as set forth in Figure 12A (SEQ ID NO:17)" be "at least about 50 amino acid residues", when SEQ ID NO: 17 is 302 amino acids long.

D) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 39, 41, 45, 49-51, 52 and 54-58 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed:

(a) " a nucleotide sequence of (b) encoding a polypeptide of at least about 75 amino acid residues of SEQ ID NO: 7, wherein the polypeptide fragment has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1" (see claim 39);

(b) "from about residues 19-302, 20-302, 21-302, 22-302, 24-302 or 28-302, wherein the polypeptide has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1" (see claims 41 and 45);

(c) "comprising a carboxy terminus at residue 302" (see claim 47);

(d) "at least about 50 amino acid residues, wherein the fragment comprises an amino acid sequence that is at least about 95% identical to an amino acid sequence as set forth in Figure 12A (SEQ ID NO: 17) and has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1" and wherein the nucleotide sequence is not the nucleotide sequence of GenBank Accession No. AB014533 or GenBank Accession No. R23544". (see claim 51); and

(e) "Accession No. R23544" (see claim 51).

Applicant's amendment, filed 1/26/04, asserts that no new matter has been added and directs support to certain sections of the instant disclosure as filed.

However, the instant specification as filed does not provide sufficient written description for:
"at least about 75 amino acid residues of SEQ ID NO: 7";
"residues 19-302, 20-302, 21-302, 22-302, 24-302 or 28-302";
"comprising a carboxy terminus at residue 302";
"at least about 50 amino acid residues ... at least about 95% identical to an amino acid sequence as set forth in Figure 12A (SEQ ID NO: 17); or
"Accession No. R23544".

The specification does not provide sufficient blazemarks nor direction for the instant claims encompassing the above-mentioned "limitations", as currently recited. The disclosure of "at least about" as well as the specific size of the 50 and 75 amino acid fragments are not readily apparent, not are the specific residues 19-302, 20-302, 21-302, 22-302, 24-302 or 28-302". In contrast to applicant's assertions, that the specific need not explicitly disclose the GenBank entries, there is a lack of sufficient specificity and particularity to GenBank R23544 in the application as filed.

The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action
Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

11. GenBank Accession No. AB014533: Claims 40, 42, 44 and 59-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

The nucleotide sequence of GenBank Accession No. AB014533 is required to practice the claimed invention. As a required element, it is essential that the nucleotide sequence of GenBank Accession No. AB014533 be supported by the instant application.

The current Sequence Listing does not appear to provide for nucleotide sequence of GenBank Accession No. AB014533.

Applicant is reminded to provide said Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the essential subject defining the claimed nucleotide sequence of GenBank Accession No. AB014533.

Applicant is reminded that to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents. See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPA 1973).

Applicant is required to provide evidence that the nucleotide sequence of GenBank Accession No. AB014533 that is to be incorporated by reference into the instant application is the same nucleotide sequence that was indicated at the time of filing of the earliest priority document relied upon (e.g. USSN 09/244,448) and indicate where the nucleotide sequence of GenBank Accession No. AB014533 is supported by said priority document.

The following is noted.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or application published by the United states or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications or (3) non-patent publications, for purposes of indicating the background of the invention or illustrating the state of the art.

The referencing application must include (1) an abstract, (2) a brief summary of the invention, (3) an identification of the referenced patent or application, (4) at least one view in the drawing in those applications admitting of a drawing, and (5) one or more claims. Particular attention should be directed to specific portions of the referenced patent or application.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

GenBank R23544: It is noted that the nucleotide sequence of GenBank R23544 would be subject to the same incorporation by reference as essential subject matter to satisfy the enablement requirements under 35USC 112, first paragraph. However, given the absence of any written support for GenBank R23544 in the application as filed, the recitation of GenBank 23544 is subject to the new matter rejection under 35USC 112, first paragraph, indicated above.

12. CRP1 / Written Description. Claims 39-41, 44, 46, 47 and 49-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The specification discloses that the nucleic acids of SEQ ID NO: 2 and SEQ ID NO: 22 encode the polypeptides of SEQ ID NO: 1 and SEQ ID NO: 21, respectively, which are mouse and human forms of CRP1. The specification also discloses in the Examples that CRP1 along with B7-RP1 is part of a costimulatory receptor-ligand pair.

There is insufficient written description encompassing "CRP1" " because the relevant identifying characteristics such as structure of other physical and/or chemical characteristics of the "CRP1" molecule, are not set forth in the specification as filed, commensurate in scope with the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Thus, the specification fails to describe sufficient identifying biochemical information, such as the appropriate amino acid or encoding nucleic acid sequences. The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant is relying upon certain biological activities and the disclosure of this limited representative number of species to support an entire genus. The instant invention encompasses any "CRP1" molecule, yet the instant specification does not provide sufficient written description as to the structural features of said "CRP1" molecules" as currently encompassed by the claims. Also, the specification does not provide for the correlation between the chemical structure and the function of the genus of "CRP1", currently encompassed by the claimed invention. The reliance on the disclosed limited examples of the "CRP1" indicated above and disclosed in the specification as filed does not support the written description of any "CRP1" molecule.

A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences for identifying a "CRP1" molecule indicated above and disclosed in the specification as filed

Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required

The instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus of "CRP1", the specification does not provide sufficient written description for the genus of "CRP1" as currently claimed".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of "CRP1" molecules; one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant's efforts to amend the claims in accordance with the suggestions of the last Office Action are acknowledged.

13. CRP1 / Enablement: Claims 40, 42, 44 and 59-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for CRP1 encoded by nucleic acids "consisting of" or "comprising" SEQ ID NO: 2 or 21 or "consisting of" or comprising" amino acids SEQ ID NO. 1 or 22; does not reasonably provide enablement for any CRP1.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification discloses that the nucleic acids of SEQ ID NO: 2 and SEQ ID NO: 22 encode the polypeptides of SEQ ID NO: 1 and SEQ ID NO: 21, respectively, which are mouse and human forms of CRP1. The specification also discloses in the Examples that CRP1 along with B7-RP1 is part of a costimulatory receptor-ligand pair.

Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies polypeptides other than those encompassed by SEQ ID NOS. 1 and 21 (or encoded by the nucleic acids set forth in SEQ ID NOS. 2 and 22). While CRP1 may have some notion of the activity of the polypeptide as a molecule associated with costimulation, claiming biochemical molecules by a particular name given to the protein (i.e. CRP1) by various workers in the field fails to distinctly claim what that protein is and what the compositions are made up of. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable any CRP1 other than those defined by SEQ ID NOS. 1 and 21 (or encoded by the nucleic acids set forth in SEQ ID NOS. 2 and 22).

Furthermore, as previously noted in the context of B7-RP1 and costimulatory molecules, the state of the art at the time the invention was made recognized that even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531, of record) showed that any of a variety of single amino acid changes can alter or abolish the ability of the CTLA4 to interact with its ligands CD80 and CD86 (B7-1 and B7-2) (e.g., summarized in Table 2). The variation in function among "B7-like" polypeptides is further emphasized by the teachings of Coyle et al. (Nature Immunol. 2:203-209 2001, of record) who show that the B7-like family members have distinct expression patterns *and distinct functions*, even though they share certain conserved amino acid residues and domain structure (see in particular Figures 2 and 3). Thus, the state of the art recognized that it is unpredictable if any particular functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

Also, it is noted that the specification as filed appears to provide sufficient guidance only with respect to limited activities of CRP1 binding to B7RP1 and stimulation of T cell proliferation and/or activation (page 42 at lines 1-6). As set forth supra, the skilled artisan at the time the invention was made recognized that polypeptides belonging to the B7 family of molecules had distinct functions. Thus the skilled artisan recognized that for any new member of the B7 family, it was unpredictable as to what particular structural or functional characteristics define a given member. In view of the limited number of working examples regarding CRP1; there does not appear to be sufficient guidance provided in the specification as filed with respect to any CRP1.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, making and using CRP1, while providing or maintaining the appropriate structural and functional characteristics of a CRP1 polypeptide would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

It is suggested that applicant limit the claims to the appropriate amino acids or nucleic acids sequences that encode CRP1 to obviate this rejection.

14. B7-RP1 / Written Description. Claims 39-41, 44, 46, 47 and 49-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The specification discloses the nucleic acids of SEQ ID NO: 11 and SEQ ID NO: 16, encoding the polypeptides of SEQ ID NO: 12 and SEQ ID NO: 17 which are two forms of a human B7-RP1 polypeptide. The specification also discloses SEQ ID NO: 6 encoding the polypeptide of SEQ ID NO: 7 which is a mouse B7-RP1 polypeptide.

Applicant's arguments, filed 1/26/04, with respect to the newly added claims have been fully considered but have not been found convincing essentially for the reasons of record set forth in the previous Office Actions.

Applicant's efforts to amend the claims in accordance with the suggestions of the last Office Action are acknowledged.

However, given the ambiguity of the claimed functional characteristics with respect to the claimed B7-RP1 encoding nucleic acid molecules as they read on nucleic acid molecules that encode "a polypeptide which has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1" as indicated above in the rejection under 35 USC 112, second paragraph; the rejection of record as it reads on the written description of the instant claims is applied herein essentially for the reasons of record. Applicant is invited to review the previous Office Actions for a more complete analysis.

As pointed out above, it is suggested that applicant amend the claims to a recitation of clear positive activities such as "stimulates T cell proliferation", "stimulates T cell activation" and "binds to CRP1" which is consistent with the disclosed activities on pages 41-42, overlapping paragraph of the instant application.

Also, as addressed herein, the recitation of the term "CRP1" is subject to rejections under 35 USC 112, first and second, paragraphs.

Applicant is invited to amend the instant claims accordingly to obviate the instant rejection.

Applicant should amend the claims to recite "fully complementary" rather than "complementary" to obviate any issues under 35 USC 112, first paragraph, written description, enablement as well as prior art. For example, see claims 39(d), 40(c) and 41(c).

15. B7-RP1 / Enablement. Claims 39-41, 44, 46, 47 and 49-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

nucleic acids "consisting of" or "comprising" SEQ ID NO:6, 11 or 16;
nucleic acids encoding polypeptides "consisting of" or "comprising" SEQ ID NO:7, 12 or 17;
nucleic acid fragments of SEQ ID NO:6, 11 or 16 in which the claim language clearly limits the fragments to *sub*sequence of SEQ ID NO:6, 11 or 16;
nucleic acids encoding polypeptides having only limited deviation from a reference sequence (e.g., a nucleic acid encoding a polypeptide 95% identical over the full length of SEQ ID NO:7) AND having a testable function supported in the specification as filed (and priority documents);

does not reasonably provide enablement for

A) nucleic "fragments" in any form in which the flanking sequences are undefined; and
B) a nucleotide sequence which "are not fully complementary".

essentially for the reasons of record set forth in the previous Office Actions.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's efforts to amend the claims in accordance with the suggestions of the last Office Action are acknowledged.

However, given the ambiguity of the functional characteristics with respect to the claimed nucleic acid molecules encoding B7-RP1 as it reads on "the polypeptide has at least one activity selected from a T cell proliferation activity, a T cell activation activity and a binding activity to CRP1" as indicated above in the rejection under 35 USC 112, second paragraph; the rejection of record as it reads on the written description of the instant claims is applied herein essentially for the reasons of record. Applicant is invited to review the previous Office Actions for a more complete analysis.

As pointed out above, it is suggested that applicant amend the claims to a recitation of clear positive activities such as "stimulates T cell proliferation", "stimulates T cell activation" and "binds to CRP1" which is consistent with the disclosed activities on pages 41-42, overlapping paragraph of the instant application.

Also, as addressed herein, the recitation of the term "CRP1" is subject to rejections under 35 USC 112, first and second, paragraphs.

Applicant is invited to amend the instant claims accordingly to obviate the instant rejection.

As indicated above, applicant should amend the claims to recite "fully complementary" rather than "complementary" to obviate any issues under 35 USC 112, first paragraph, written description, enablement as well as prior art. For example, see claims 39(d), 40(c) and 41(c).

9. The previous rejection under 35 U.S.C. 112, first paragraph, written description / new matter has been obviated by applicant's cancellation of claims 36 and 37.

Claim Rejections – 35 U.S.C. §§ 102 and 103

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 39, 41 and 52-58 are rejected under 35 U.S.C. 102(a) as being anticipated by Ishikawa et al (DNA Res. June 1998; 5:169-176, of record, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999, of record).

Applicant's arguments, filed 1/26/04, with respect to the newly added claims have been fully considered but have not been found convincing.

Applicant argues that the nucleic acids and corresponding amino acids disclosed by GenBank Accession No. AB014553 differ from applicant's invention in that the AB014553 does not teach a polypeptide with the same or even similar N- and C-termini as the polypeptides set forth in SEQ ID NOS: 12 and 17.

However, the claims are not limited to nucleic acids that encode the polypeptides set forth in SEQ ID NOS 12 and 17. In addition, the claims do not recite "fully complementary", leaving the claims subject to prior art that teaches nucleic acids that are not fully complementary.

The following of record is reiterated for applicant's convenience.

Ishikawa et al. teach KIAA0653, and that the sequence information for the cDNA of KIAA0653 is available under accession number AB014553 (see entire document, but especially Table 1, first column). Ishikawa et al. also teach that the protein product of KIAA0653 was produced by in vitro translation (see comments in Section 2.1 on page 169 regarding original screening method); therefore, the cDNA clone KIAA0653 must also have been operably linked to an expression control sequence and placed in a host cell.

Ishikawa et al. teach that the KIAA0653 has homology to CD80, the original member of the B7 family of co-stimulatory proteins (e.g. see Table 2, page 175).

KIAA0653 encompasses the entire nucleotide sequence set forth in SEQ ID NO:11. Thus KIAA0653 is an isolated nucleic acid comprising:

the nucleotide sequence as set forth in SEQ ID NO:11;

the nucleotide sequence encoding a polypeptide as set forth in SEQ ID NO:12 from residues 1-288;

a nucleotide sequence encoding a polypeptide fragment of at least about 25, 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 12;

a nucleotide sequence comprising a fragment of at least about 10, 15, 20, 25, 50, 75, 100 or greater than 100 nucleotides of SEQ ID NO:11; and

a nucleotide sequence which hybridizes under high stringency conditions to SEQ ID NO:11.

KIAA0653 also encompasses the nucleic acid sequence as set forth in SEQ ID NO:16 from approximately nucleotide 209 to 1098. Thus KIAA0653 is also a nucleotide sequence encoding a polypeptide fragment of at least about 25, 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 17, and a nucleotide sequence comprising a fragment of at least about 10, 15, 20, 25, 50, 75, 100 or greater than 100 nucleotides of SEQ ID NO:16.

Applicant argues in the Remarks filed 5/5/03 that Ishikawa et al. is a non-enabling reference because it does not by itself place the public in possession of the invention without the teachings of the evidentiary reference of GenBank Accession No. AB014553, which is not available as prior art.

Applicant is again reminded that no more of the reference is required than that it sets forth the substance of the invention. The instant limitations, including encoding a polypeptide with at least one activity "characteristic of B7RP1", would be inherent properties of KIAA0653.

The reference teachings thus anticipate the instant claimed invention.

The rejection is therefore maintained as applied to the amended claims.

18. Claims 39-41 and 52-57 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. R23544 (GI:778432, released 20 April 1995, of record).

Applicant's arguments, filed 1/26/04, with respect to the newly added claims have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues that the nucleic acids and corresponding amino acids disclosed by GenBank Accession No. AB014553 differ from applicant's invention in that the AB014553 does not teach a polypeptide with the same or even similar N- and C-termini as the polypeptides set forth in SEQ ID NOS: 12 and 17.

However, the claims are not limited to nucleic acids that encode the polypeptides set forth in SEQ ID NOS 12 and 17. In addition, the claims do not recite "fully complementary", leaving the claims subject to prior art that teaches nucleic acids that are not fully complementary.

The following of record is reiterated for applicant's convenience.

R23544 is an isolated nucleic acid sequence 365 nucleotides in length that is 100% identical to instant SEQ ID NO:11 from nucleotide 407 to 771.

Instant SEQ ID NO:16 comprises instant SEQ ID NO:11; therefore R23544 is also 100% identical to instant SEQ ID NO:16 from approximately nucleotide 606 to 970.

R23544 is also taught to be a cDNA insert of a clone that is propagated in the lab host DH10B, a prokaryotic cell.

R23544 is also:

a nucleotide sequence encoding a polypeptide fragment of at least about 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 12 or instant SEQ ID NO:17;

a nucleotide sequence comprising a fragment of at least about 75, 100 or greater than 100 nucleotides of SEQ ID NO:11 or SEQ ID NO:16; and

a nucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:11 or SEQ ID NO:16.

The activity the polypeptide encoded by a given nucleic acid is inherent to the sequence. Applicant has provided no evidence that the polypeptide encoded by R23544 would not possess at least one activity characteristic of B7RP1.

Applicant is again reminded that no more of the reference is required than that it sets forth the substance of the invention. The instant limitations would be inherent properties of R23544.

The reference teachings thus anticipate the instant claimed invention and the rejection is maintained as applied to the amended and newly added claims.

19. Claims 39, 41 and 52-57 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. AA510455 (GI:2248309, released 08 July 1997, of record).

Applicant's arguments, filed 1/26/04, with respect to the newly added claims have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues that the nucleic acids and corresponding amino acids disclosed by GenBank Accession No. AB014553 differ from applicant's invention in that the AB014553 does not teach a polypeptide with the same or even similar N- and C-termini as the polypeptides set forth in SEQ ID NOS: 12 and 17.

However, the claims are not limited to nucleic acids that encode the polypeptides set forth in SEQ ID NOS 12 and 17. In addition, the claims do not recite "fully complementary", leaving the claims subject to prior art that teaches nucleic acids that are not fully complementary.

The following of record is reiterated for applicant's convenience.

AA510455 is an isolated nucleic acid sequence 440 nucleotides in length that is 99.7% identical to instant SEQ ID NO:6 from nucleotide 1 to 309, and 100% identical to SEQ ID NO:6 from nucleotide 120-309.

AA510455 is also taught to be a cDNA insert of a clone that is propagated in the lab host DH10B, a prokaryotic cell.

AA510455 is also:

a nucleotide sequence encoding a polypeptide fragment of at least about 50 amino acid residues of instant SEQ ID NO:7;

a nucleotide sequence comprising a fragment of at least about 75, 100 or greater than 100 nucleotides of SEQ ID NO:6; and

a nucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:6.

The activity the polypeptide encoded by a given nucleic acid is inherent to the sequence. Applicant has provided no evidence that the polypeptide encoded by AA510455 would not possess at least one activity characteristic of B7RP1.

Applicant is again reminded that no more of the reference is required than that it sets forth the substance of the invention. The instant limitations would be inherent properties of AA510455.

The reference teachings thus anticipate the instant claimed invention and the rejection is maintained as applied to the amended and newly added claims.

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al (DNA Res. June 1998; 5:169-176, of record, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999, of record) in view of Linsley et al. (U.S. Pat. No. 5,580,756, of record) essentially for the reasons of record..

Applicant's arguments, filed 1/26/04, with respect to the newly added claims have been fully considered but have not been found convincing.

Applicant argues that the nucleic acids and corresponding amino acids disclosed by GenBank Accession No. AB014553 differ from applicant's invention in that the AB014553 does not teach a polypeptide with the same or even similar N- and C-termini as the polypeptides set forth in SEQ ID NOS: 12 and 17.

However, the claims are not limited to nucleic acids that encode the polypeptides set forth in SEQ ID NOS 12 and 17. In addition, the claims do not recite "fully complementary", leaving the claims subject to prior art that teaches nucleic acids that are not fully complementary.

The claims are drawn to a host cell comprising a B7RP-1 nucleic acid, wherein the host cell is a eukaryotic cell or a prokaryotic cell.

Ishikawa et al. have been discussed supra, and in brief, teach a B7 (CD80)-related polypeptide encoded by KIAA0653.

Although a host cell was necessarily present in the teachings of Ishikawa et al. since the protein was expressed, Ishikawa et al. do not explicitly teach either a eukaryotic host cell or a prokaryotic host cell comprising KIAA0653.

However, as noted supra, Ishikawa et al. do teach that the ordinary artisan at the time the invention was made was motivated to express the protein so that the protein could be further characterized.

Linsley et al. teach the B7 (CD80) polypeptide and its characterization as a co-stimulatory protein (see entire document, e.g., "Summary of the Invention" at columns 3-4).

Linsley et al. teach that the B7 protein could be expressed in either a prokaryotic or eukaryotic host cells (see columns 7-9 in particular).

The ordinary artisan at the time the invention was made would therefore have found it obvious to express the protein product of KIAA0653 in either a eukaryotic or prokaryotic host cell. The ordinary artisan at the time the invention was made would have been motivated to express the protein product of KIAA0653 using each type of host cell, since each system has its own advantages and disadvantages (e.g., glycosylation patterns, ease of isolation of protein, etc.). Expression of proteins in either eukaryotic or prokaryotic hosts was a matter of common practice at the time the invention was made, such that the ordinary artisan would have had a reasonable expectation that both types of host cells could be used. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

16. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 39-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of 1-7 copending application Serial No. 09/728,0420 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and copending claims are drawn to the same or nearly the same nucleic acids encoding the same costimulatory molecules as well as the associated vectors, host cells and methods of producing recombinant proteins.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. Claims 42-43 and 48 appear to be free of the prior art and, in turn, allowable.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
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